SAFETY DATA SHEET

1. Identification

Product identifier **IMITREX INJECTION**

Other means of identification

Synonyms IMITREX INJECTION 4 MG/0.5 ML * IMITREX INJECTION 6 MG/0.5 ML * IMIGRAN 6 MG INYECTABLE * MIGRANE 6 MG/0,5 ML, SOLUTION INJECTABLE POUR VOIE SOUS-CUTANEE EN SERINGUE PRE-REMPLIE * IMIGRAN 6 MG/0,5 ML RAZTOPINA ZA INJICIRANJE * IMIGRAN 6 MG/0,5 ML - SPRITZAMPULLEN * IMIGRAN 6 MG/0,5 ML SOLUZIONE INIETTABILE PER USO SOTTOCUTANEO * IMIGRAN 6 S.C. OPLOSSING VOOR INJECTIE VOOR SUBCUTAAN GEBRUIK * IMIGRAN ΕΝΈΣΙΜΟ ΔΙΆΛΥΜΑ * IMIGRAN OLDATOS INJEKCIÓ + AUTOINJEKTOR * IMITREX STATDOSE SYSTEM * IMITREX STATDOSE PEN * IMITREX INJECTION CATRIDGE PACK * IMITREX SINGLE DOSE VIAL 6 MG * IMIGRAN SUBJECT TREATMENT PACK 0.5 ML * IMIGRAN SUBJECT REFILL PACK 0.5 ML * IMIGRAN INJECTION 12 MG/ML * IMIGRAN 12 MG/ML INJEKTIONESTE, LIUOS * IMIGRAN 12 MG/ML STUNGULYF, LAUSN * IMIGRAN 12 MG/ML INJEKSJONSVÆSKE, OPPLØSNING * IMIGRAN 12 MG/ML INJEKTIONSVÄTSKA, LÖSNING * IMIGRANE SYRINGE * SUMATRIPTAN SUCCINATE, FORMULATED PRODUCT

Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SUMATRIPTAN SUCCINATE	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-MET HYL-1H-INDOLE-5-METHANESULPHON AMIDE SUCCINATE 357 (GW ACN) 455 SUMATRIPTAN STANDARD REFERENCE TEST MIX 1 (ANZ) 6666 SUMATRIPTAN STANDARD REFERENCE TEST MIX 12 (ANZ) 466 SUMATRIPTAN STANDARD REFERENCE TEST MIX 13 (ANZ) 599 SUMATRIPTAN STANDARD REFERENCE TEST MIX 18 (ANZ)	103628-48-4	1.1 - < 1.7
SODIUM CHLORIDE	COMMON SALT ROCK SALT SODIUM MONOCHLORIDE SALT SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	0.7
Other components below reportable levels			>98.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: difficult or irregular breathing; abnormal nervous system sensations; feelings of heaviness or pressure. Nausea, vomiting. May cause drowsiness or dizziness.

Indication of immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Note
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)	15 MIN STEL	100 mcg/m3	
	8 HR TWA	50 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Applicator pen. and
Vial.

Color

Not available.

Odor	Not available.
Odor threshold	Not available.
pH	4.5 - 5
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: difficult or irregular breathing; abnormal nervous system sensations; feelings of heaviness or pressure. Nausea, vomiting. May cause drowsiness and dizziness.

Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)		
Acute		
Oral		
LD50	Mouse	> 1500 mg/kg
	Rat	> 2000 mg/kg
Chronic		
Oral		
NOAEL	Rat	5 mg/kg/day, 18 months
TD	Rat	>= 50 mg/kg/day
Subchronic		
Oral		
TD	Dog	<= 50 mg/kg/day, 60 weeks

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

SUMATRIPTAN SUCCINATE
Acute dermal irritation
Result: Negative

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

SUMATRIPTAN SUCCINATE
OECD 405
Result: Mild irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization No studies have been conducted.

Skin sensitization None known. This product is not expected to cause skin sensitization.

Sensitization

SUMATRIPTAN SUCCINATE
Topical
Result: Negative
Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

SUMATRIPTAN SUCCINATE
<= 1000 mg/kg Micronucleus Test
Result: Negative
Species: Rat
Ames, GLP
Result: Negative
Bacterial Fluctuation Test
Result: Negative
Chromosomal Aberration Assay In Vitro, GLP
Result: Negative
HPRT gene mutation in human lymphocytes
Result: Negative
WHO Nitrosation Assay
Result: Negative
Yeast Mutation Assay
Result: Negative

Carcinogenicity Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

Carcinogenicity

SUMATRIPTAN SUCCINATE

10 - 160 mg/kg/day
Result: Negative
Species: Mouse
10 - 160 mg/kg/day
Result: Negative
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

SUMATRIPTAN SUCCINATE

>= 100 mg/kg/day Embryo-foetal development - Oral
Result: Maternal toxicity; adverse foetal effects
Species: Rat
>= 100 mg/kg/day Embryo-foetal development- Oral
Result: Maternal toxicity; adverse foetal effects
Species: Rabbit
100 mg/kg/day Fertility
Result: Reduced success of insemination.
Species: Rat
1000 mg/kg/day Pre- and Post-natal development
Result: Maternal toxicity; adverse foetal effects
50 mg/kg/day Embryo-foetal development- Oral
Result: NOAEL
Species: Rabbit
60 mg/kg/day Embryo-foetal development - Oral
Result: NOAEL
Species: Rabbit

Specific target organ toxicity - single exposure Circulatory system.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not established.

Chronic effects Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test

Components		Species	Test Results
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 750 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	36 mg/l, 72 hours OECD 201
	NOEC	Green algae (Scenedesmus subspicatus)	12.5 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia pulex)	290 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia pulex)	200 mg/l, 48 hours
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days Static renewal test, EPA Method 1002
	NOEC	Daphnia	32 mg/l, 8 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

SUMATRIPTAN SUCCINATE 290 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SUMATRIPTAN SUCCINATE > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SUMATRIPTAN SUCCINATE 100 %, 16 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
17 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

SUMATRIPTAN SUCCINATE 1 %, 28 days

Percent degradation (Aerobic biodegradation-soil)

SUMATRIPTAN SUCCINATE 32 - 40 %, 64 days, Soil

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SUMATRIPTAN SUCCINATE 0.93 (Measured).

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SUMATRIPTAN SUCCINATE 3.52 - 3.57 Measured

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-24-2018

Revision date 05-24-2018

Version # 15

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 0
Instability: 0

References GSK Hazard Determination

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision information This document has undergone significant changes and should be reviewed in its entirety.